

UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS

IN RE: NEW ENGLAND COMPOUNDING  
PHARMACY, INC. PRODUCTS LIABILITY  
LITIGATION

MDL No. 2419

THIS DOCUMENT RELATES TO:

Dkt. No. 1:13-md-2419 (RWZ)

All Suits Naming St. Thomas Outpatient  
Neurosurgical Center

**PLAINTIFFS' STEERING COMMITTEE'S MEMORANDUM  
IN SUPPORT OF MOTION UNDER RULE 54(B) FOR RECONSIDERATION  
OF THE COURT'S FEBRUARY 29, 2016, OPINION AND ORDER**

Respectfully, the Plaintiffs' Steering Committee ("PSC") asks the Court to reconsider its February 29, 2016, Opinion and Order.<sup>1</sup> There, the Court concluded that:

1. because there is overlap between the Tennessee Products Liability Act ("PLA") and the Tennessee Healthcare Liability Act ("HCLA"), their conflicting liability and damages provisions preclude application of both, and force a choice between them; and
2. because under Tennessee law the more specific statute should be applied, and here "the parties agree that ... the [HCLA is the more specific statute," the PLA is inapplicable here.

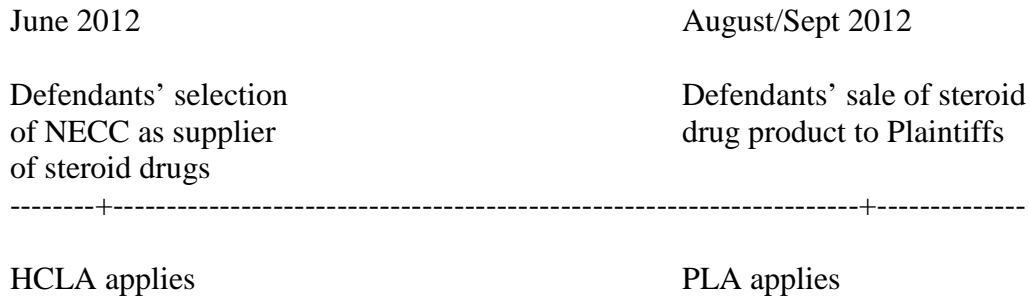
But the Court has erred, and should reconsider its opinion because:

1. the HCLA and the PLA can (and therefore must, per Tennessee law) be construed harmoniously, precisely because the Tennessee Legislature did not intend them to be in conflict, nor intend for one of them to trump the other. Here, the statutes can be construed harmoniously because they each primarily apply to different events in the timeline—the HCLA primarily

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<sup>1</sup> [Dkt. No. 2700].

applies to the Tennessee Defendants’<sup>2</sup> negligent selection of NECC as the supplier of the steroid drug and their unlawful purchase of that steroid drug from NECC, while the PLA primarily applies to the later sale of that drug product to the Plaintiffs. These are two different events, as illustrated by the diagram below:



2. Even if the HCLA and the PLA were in conflict (which they are not), the PLA would apply here because it is the more specific statute.

In light of these errors, the PSC respectfully asks the Court to reconsider its decision.

#### **RULE 54 STANDARD**

Under Rule 54(b), a district court may revisit an interlocutory decision that is not immediately appealable, including a partial dispositive motion, at any time prior to the entry of final judgment.<sup>3</sup> A motion for reconsideration is appropriate when there is a need to correct a

<sup>2</sup> Reflecting the nomenclature used in the Court’s opinion, “Tennessee Defendants” or “defendants” as used herein refers to Saint Thomas Outpatient Neurosurgical Center, LLC (“St. Thomas Neurosurgical”); Howell Allen Clinic, P.C.; John Culclasure, MD; Debra Schamberg, RN, CNOR; and Vaughan Allen.

<sup>3</sup> Fed. R. Civ. P. 54(d); *Perez-Ruiz v. Crespo-Guillen*, 25 F.3d 40, 42 (1<sup>st</sup> Cir 1994) (“Interlocutory orders, including denials of motions to dismiss, remain open to trial court reconsideration, and do not constitute the law of the case.”); *Nieves-Luciano v. Hernandez-Torres*, 397 F.3d 1, 4 (1<sup>st</sup> Cir. 2005) (“[I]nterlocutory orders from which no immediately appeal may be taken . . . remain open to trial court reconsideration until the entry of the judgment.”) (quotation omitted).

clear error of law or to prevent manifest injustice.<sup>4</sup> A Court should also reconsider a decision in which it “has patently misunderstood a party” or “has made an error not of reasoning but apprehension.”<sup>5</sup>

### **ARGUMENT**

In its February 29, 2016, Opinion and Order, the Court erred in concluding the the HCLA and the PLA irreconcilably conflict here. Proper application of Tennessee’s rules of statutory construction indicate that both statutes can apply here; moreover, the legislative history makes clear that the Tennessee Legislature intended the statutes to be construed harmoniously and did not intend for either one to trump the other.

The Court also erred in its understanding of the parties’ positions—neither the PSC nor the Defendants took the position that the HCLA was the more specific statute; in fact, the PSC argued just the opposite: that the PLA was the more specific statute. It is unjust for the Court to base its opinion on a misapprehension of the parties’ positions, as it has done here.

For these two reasons, the Court should reconsider its February 29, 2016, Order and Opinion.

**I. Tennessee’s Rules of Statutory Construction and The Legislative History of the Statutes Lead to The Conclusion That The HCLA and The PLA Do Not Conflict Here.**

**A. Tennessee Law Requires Statutes to Be Construed Harmoniously if Possible – And They Can Be Here.**

The Tennessee Supreme Court requires that, when a court construes two Tennessee statutes, a construction that places “one statute in conflict with another must be avoided;

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<sup>4</sup> *Davis v. Lehane*, 89 F. Supp. 2d 142 (D. Mass. 2000); *see also United States v. Allen*, 573 F.3d 42, 53 (1<sup>st</sup> Cir. 2009).

<sup>5</sup> *Ruiz Rivera v. Pfizer Pharms., LLC*, 521 F.3d 76, 82 (1<sup>st</sup> Cir. 2008).

therefore, [a court] must resolve any possible conflict between statutes in favor of each other, so as to provide a harmonious operation of the laws.”<sup>6</sup> Furthermore, in Tennessee, “the repeal of a statute by implication is not favored and there must be an irreconcilable conflict or repugnancy between the statutes that is plain and unavoidable to work a suspension of the earlier statute.”<sup>7</sup>

Therefore, as the PSC argued: (1) in construing the PLA here, the Court was required to employ the principle of *expressio unius est exclusio alterius* and was required to give effect to all of the language set forth in the statute; (2) when construing the interaction between the PLA and the HCLA, the Court was required to construe the statutes in harmony if at all possible, so as to promote “harmonious operation of the laws”;<sup>8</sup> (3) before reaching the issue of whether one statute should prevail over the other, the Court was required to determine that there was “an

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<sup>6</sup> *Graham v. Caples*, 325 S.W.3d 578, 582 (Tenn. 2010); *see also State ex rel. Metro. Gov’t of Nashville v. Spicewood Creek Watershed Dist.*, 848 S.W.2d 60, 62 (Tenn. 1993) (“[C]ourts should avoid a construction which places one statute in conflict with another,” and “potential conflicts between statutes should be resolved in favor of each statute, if possible, to provide a harmonious operation of the laws”) (citing *Parkridge Hosp., Inc. v. Woods*, 561 S.W.2d 754, 755 (Tenn. 1978)).

<sup>7</sup> *Oliver v. King*, 612 S.W.2d 152, 154 (Tenn. 1981); *see also Spence v. Miles Lab.*, 810 F. Supp. 952, 963-64 (E.D. Tenn. 1992) (finding no irreconcilable conflict between PLA and a section of the Tennessee Code specific to the handling of AIDS-contaminated blood products, and construing statutes to be “harmonious”); *Bd. of Educ. of Shelby Cty. v. Memphis Bd. of Educ.*, 2011 U.S. Dist. LEXIS 87803, at \*124-126 (W.D. Tenn. Aug. 8, 2011) (finding that there was a construction that gave meaning and effect to the language of all the provisions at issue, rejecting a proposed construction of the statutes that would place them in conflict, and adopting the harmonious construction of both laws because “the Court may only conclude that [one law] repealed the [other law] by implication if no fair and reasonable construction permits them to stand together and the conflict is irreconcilable”).

<sup>8</sup> *Graham*, 325 S.W.3d at 582 (internal brackets and quotation omitted); *see also Spicewood Creek*, 848 S.W.2d at 62 (“[C]ourts should avoid a construction which places one statute in conflict with another,” and “potential conflicts between statutes should be resolved in favor of each statute, if possible, to provide a harmonious operation of the laws”) (citing *Parkridge Hosp*, 561 S.W.2d at 755).

irreconcilable conflict or repugnancy between the statutes that is plain and unavoidable”,<sup>9</sup> and (4) if the Court found that the statutes could not be read harmoniously and that an irreconcilable conflict existed, then the more specific provision—here the PLA—should control.<sup>10</sup> This Court is obligated to undertake that analysis with respect to the PLA and the HCLA,<sup>11</sup> but failed to do so here, which was a clear error under binding Tennessee Supreme Court precedent.

In its February 29, 2016 Opinion and Order, the Court held that the HCLA and PLA were both broadly worded, that both statutes therefore “could” apply to the facts at issue, and that both statutes “ostensibly control.”<sup>12</sup> Without attempting to determine whether the statutes could be read harmoniously, the Court stated that the overlap “force[s] a choice between” the two statutes.

But the subject statutes *can* be construed harmoniously here because each governs separate transactions. The HCLA governs claims alleging that a healthcare provider caused harm through the provision of medical services<sup>13</sup>, while the PLA governs claims that do not arise from the healthcare providers’ conduct or services, *i.e.*, claims for harm caused by products.<sup>14</sup> That construction of the two statutes gives meaningful effect to both, as both statutes govern within their respective spheres.

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<sup>9</sup> *Oliver v. King*, 612 S.W.2d 152, 154 (Tenn. 1981); *see also Spence v. Miles Lab.*, 810 F. Supp. 952, 963-64 (E.D. Tenn. 1992) (finding no irreconcilable conflict between PLA and a section of the Tennessee Code specific to the handling of AIDS-contaminated blood products, and construing statutes to be “harmonious”).

<sup>10</sup> *Graham*, 325 S.W.3d at 582.

<sup>11</sup> *See also Ellwest Stereo Theater, Inc. v. Boner*, 718 F. Supp. 1553, 1578 (M.D. Tenn. 1989) (applying Tennessee principles and finding no irreconcilable conflict among Tennessee statutes at issue).

<sup>12</sup> Dkt. No. 2700, at p. 5.

<sup>13</sup> Tenn. Code Ann. § 29-26-101(A)(1).

<sup>14</sup> Tenn. Code Ann. § 29-28-102(5) & (6).

In this case, the statutes apply to different transactions in the timeline of events – the HCLA applies to the Tennessee Clinic Defendants’ negligent selection of NECC as the supplier of the steroid drug and their unlawful purchase of it from NECC, while the PLA applies to the sale of that steroid drug product to the Plaintiffs (as illustrated by the diagram above).

**1. Tennessee Defendants’ June 2012 Selection of NECC as supplier of MPA Is Governed by the HCLA**

A cause of action under the HCLA turns on whether the defendant medical provider breached a duty of care to the plaintiff, and in so doing caused injury to the plaintiff.<sup>15</sup> Here, in June 2012, the Tennessee Defendants chose NECC as its supplier of the steroid drug and began purchasing it from NECC without patient specific prescriptions. If, as Plaintiffs allege, those actions by the Tennessee Defendants violated the relevant standard of care, then those Defendants can be held liable under the HCLA for injuries legally caused by those breaches of the standard of care.

**2. Tennessee Defendants’ Sales of MPA to Plaintiffs in August and September of 2012 are Transactions Governed by the PLA.**

The PLA holds “sellers,” including medical providers, liable for selling products to their patients, provided that the original manufacturer is insolvent or cannot be served with process.<sup>16</sup> Here, in August and September 2012 – months after their selection of NECC and purchase of the steroid drug from NECC – the Tennessee Defendants sold the steroid drug product to Plaintiffs during the course of Plaintiffs’ injections. The product sold to Plaintiffs – the contaminated steroid – is what caused Plaintiffs’ injuries. Each product sale of the steroid to Plaintiffs is governed by the PLA.

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<sup>15</sup> Tenn. Code Ann. § 29-26-102(b).

<sup>16</sup> Tenn. Code Ann. § 29-28-106.

While it is true that Tennessee Defendants also provided a medical service during the July and August 2012 transactions and that the HCLA would apply to that “service”, that does not change the analysis here. The common wrongdoing Plaintiffs allege regarding the July and August 2012 transactions is the sale of a product – the steroid drug – to Plaintiffs, which product caused Plaintiffs’ injuries. In other words, had Tennessee Defendants sold Plaintiffs a non-defective product (i.e. a steroid from an FDA-regulated manufacturer, such as Pfizer), Plaintiffs would not have been injured.<sup>17</sup>

**B. Legislative History Shows the Tennessee Legislature Intended for the HCLA and PLA to Be Construed Harmoniously**

It is clear that the Tennessee Legislature intended the HCLA and the PLA to operate harmoniously, because the Legislature worked on both statutes simultaneously as part of the same Act, the Civil Justice Act of 2011 (“CJA”). As part of the CJA, the Tennessee Legislature both enacted the HCLA and rewrote the PLA.<sup>18</sup> The Tennessee Legislature therefore considered both statutes at the same time (amending one, enacting the other) and saw no conflict.<sup>19</sup> If it had seen such a conflict, the legislature could have abrogated the PLA, or otherwise indicated how

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<sup>17</sup> This gives the lie to Tennessee Defendants’ argument that it is impossible to separate the product from the medical treatment ([Dkt. 2463] at 20)—it is not impossible to do so here because providing the same treatment while selling Plaintiffs a different product (say, Pfizer-made steroid) would have avoided the injury to Plaintiffs.

<sup>18</sup> See 2011 Tenn. HB 2008, 2011 Tenn. Pub. Acts 510 (enacted June 16, 2011). With respect to the PLA, the Civil Justice Act of 2011 amended PLA § 104 (Tenn. Code Ann. § 29-28-104), relating to damages, and PLA § 106 (Tenn. Code Ann. § 29-28-106), which relates to the conditions under which a “seller” can be held liable under the PLA at the same time. Effectively, in its amendments to PLA § 106, the Tennessee legislature authorized lawsuits against “sellers” as defined in § 102(7), provided that (among other things) the manufacturer of the product at issue was insolvent.

<sup>19</sup> This is contrary to the misleadingly incomplete version of the legislative history offered by the Tennessee Defendants, who state that the HCLA was enacted after the PLA, but fail to mention that the HCLA was enacted in the very same piece of legislation that rewrote the PLA. [Dkt. 2463 at 21].

such a conflict should be resolved, in the same Civil Justice Act that created the HCLA. But it did not.

The PSC submits that, once the Court conducts the requisite analysis, the Court will conclude that the statutes can be read harmoniously within their spheres, consistent with the intent of the Tennessee legislature. Accordingly, under an appropriate analysis, the Court will conclude that the PLA applies to the sales of the steroid in August and September 2012 that are at issue – as opposed to the distinct transaction by the Tennessee Defendants in choosing to purchase the steroid drug from NECC in June 2012, which is governed by the HCLA.

## **II. The Court Mistook the Parties' Positions Concerning Which Is the More Specific Statute.**

Reconsideration is also proper where, as here, a Court “has patently misunderstood a party” or “has made an error not of reasoning but apprehension.”<sup>20</sup> Here, the Court correctly held that where two statutes are in conflict, Tennessee courts apply the more specific statute in lieu of the more general one. But the Court then went on to state “The parties agree that between the []PLA and the []HCLA, the []HCLA is the more specific statute...” and reasoned “The []HCLA therefore takes precedence, rendering the []PLA inapplicable in these cases.”<sup>21</sup>

But the parties here plainly *do not agree* that the HCLA is the more specific statute—in fact, the PSC’s position was the exact opposite: that the PLA was the more specific statute, because Plaintiffs’ injuries here were caused by the Defendants’ sale to them of contaminated drug products.<sup>22</sup> And the Tennessee Defendants, for their part, took no position at all on the matter in any of their briefing. It is therefore unclear to the PSC why the Court assumed that the

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<sup>20</sup> *Ruiz Rivera*, 521 F.3d at 82.

<sup>21</sup> Dkt. 2700 at 5.

<sup>22</sup> Dkt. 2508 at 5.



PSC would have agreed with anyone (let alone Defendants) that the HCLA is the more specific statute, or why the Court assumed that Defendants had taken a position on this issue. It is manifestly unjust for the Court to base its opinion on asserted concessions of law that the parties did not actually make.

As explained above, the HCLA and the PLA are not in conflict here. But if they were, the PLA is plainly the more specific statute. The PLA applies to any cause of action against a manufacturer or seller that is “caused by” a defective product.<sup>23</sup> By contrast, the HCLA applies to injuries “related to the provision of . . . health care services...”<sup>24</sup> “Caused by” is a more specific, limited term than “related to”—for example, an injury could be “related” to the provision of health care services without being “caused by” the provision of those services, but proving a PLA claim would require a showing of proximate causation and the associated elements – over and above simple “relatedness.”<sup>25</sup> As in *Graham*, where the court found the term “issued” was more specific and limited than the term “sues out”, and therefore the statute using the more specific term “issued” took precedence over the conflicting statute that used the more general term,<sup>26</sup> the Court here should find that the statute using the more specific term “caused by” – the PLA – takes precedence over the HCLA.

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<sup>23</sup> Tenn. Code Ann. § 29-28-103(a).

<sup>24</sup> Tenn. Code Ann. § 29-26-101(a)(2).

<sup>25</sup> See, e.g., *Whaley v. Rheem Mfg. Co.*, 900 S.W.2d 296, 300 (Tenn. Ct. App. 1995) (“It almost goes without saying that the identified product defect must be the proximate cause of the plaintiff’s injury.”).

<sup>26</sup> *Graham*, 325 S.W.3d at 582 (“Further, while ‘suing out’ is a broad and general term, susceptible to various definitions in the context of [the statute], the definition of ‘issued’ considered in its statutory context is specific and limited and, therefore, the former must bow to the latter under the rule that a specific statutory provision shall be given effect over a conflicting general provision.”).

### III. CONCLUSION

In sum, the Court's failure to properly analyze whether the PLA and HCLA can be read harmoniously and therefore not in conflict constituted clear error. It was also manifestly unjust for the Court to rule against the PSC based on concessions of law that the PSC did not make. These errors merit reconsideration of the Court's February 29, 2016 Opinion and Order, the denial of the defendants' Rule 56 motion, and the entry of judgment to the plaintiffs on their PLA claims.<sup>27</sup>

Dated: March 16, 2016

Respectfully submitted,

/s/ Benjamin A. Gastel

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*Plaintiffs' Steering Committee and TN Chair*

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<sup>27</sup> At a minimum, the Court's analysis will demonstrate that there is at least a genuine dispute of material fact to be decided by the jury as to whether the defendants' constitute "sellers" under the PLA.

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*Plaintiffs' Steering Committee*

**CERTIFICATE OF SERVICE**

I, Benjamin A. Gastel, hereby certify that I caused a copy of the foregoing to be filed electronically via the Court's electronic filing system. Those attorneys who are registered with the Court's electronic filing system may access these filings through the Court's system, and notice of these filings will be sent to these parties by operation of the Court's electronic filing system.

Dated: March 16, 2016

/s/ Benjamin A. Gastel  
Benjamin A. Gastel